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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,502	12/14/2005	Chris D. Geddes	026228-101.02-029	6557
24239 7590 03/16/2011 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709				
EXAMINER				
BERTAGNA, ANGELA MARIE				
ART UNIT		PAPER NUMBER		
1637				
MAIL DATE		DELIVERY MODE		
03/16/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/536,502

**Applicant(s)**

GEDDES ET AL.

**Examiner**

ANGELA BERTAGNA

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.5-10, 12-16, 18, 20-22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1.5-10, 12-16, 18, 20-22 and 24-27 is/are rejected.
- 7) ☒ Claim(s) 1.16 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No.(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of the Application**

1. Applicant's response filed on January 6, 2011 is acknowledged. Claims 1, 5-10, 12-16, 18, 20-22, and 24-27 are currently pending. In the response, claims 1, 8, and 16 were amended.

The following include new grounds of rejection necessitated in part by Applicant's amendments to the claims. Any previously made rejections or objections not reiterated below have been withdrawn. Applicant's arguments filed on January 6, 2011 have been fully considered and are discussed in the "Response to Arguments" section. Since not all of the issues raised below were necessitated by Applicant's amendment, this office action is **NON-FINAL**.

### **Specification**

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not provide proper antecedent basis for the subject matter of claims 14 and 27, which recite that the fluorophore comprises Rhodamine B, rose bengal, or fluorescein isothiocyanate. The specification only provides proper antecedent basis for the use of said fluorophores and not for fluorophores that may comprise additional elements as recited in claims 14 and 17 (see pages 10-12). This issue could be obviated by amending claims 14 and 17 to recite "wherein the fluorophore is Rhodamine B, rose bengal, or fluorescein isothiocyanate".

### **Claim Objections**

3. Claims 1 and 16 are objected to because of the following informalities: The phrases "wherein each of the capture nucleotide sequence probe is the same" and "wherein each of the free nucleotide sequence probe is the same" are grammatically incorrect. Replacing the word "probe" with "probes" or deleting the words "of the" is suggested.

Claim 1 is also objected to because of the following informalities: The full name of B. anthracis should appear in the claim before the abbreviated form is used.

Claim 22 is objected to because of the following informalities: This claim contains a typographical error where "luminomete" is recited for "luminometer".

Appropriate correction is required.

### **Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph (New Matter)**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-10, 12-16, 18, 20-22, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Section 2163.03 of the MPEP states, "An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed." In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989).

Section 2163.06 of the MPEP states, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement." In re Rasmussen, 650 F.2d 1212, 21 1 USPQ 323 (CCPA 1981).

Claims 1, 5-10, 12-16, 18, 20-22, and 24-27 are drawn to a fluorescence-based hybridization method for detecting the presence of *Bacillus anthracis* in a sample. Claims 16, 18, 20-22, and 24-27 are drawn to a fluorescence-based hybridization method for detecting the presence of a target pathogen, such as *B. anthracis*, in a sample. Independent claims 1 and 16 have been amended to recite that the method comprises providing a system that consists of: (i) a layer of immobilized metal particles on a surface substrate, and (ii) a plurality of capture nucleotide sequence probes attached to the metal particles. The response does not identify the portions of the original disclosure that provide support for the amendment. The "consisting of" language in independent claims 1 and 16 excludes systems comprising any additional elements. Such systems are not adequately supported by the original disclosure, because only systems consisting of three components are described (see, for example, pages 5-7, where the systems are described as consisting of a metallized substrate, immobilized capture probes, and free probes). See also MPEP 2163.05, which states that deleting an essential element can introduce new matter if support for said deletion is not found in the original disclosure. In this case, the inclusion of the free probe in the system is disclosed as an essential component, and, therefore its exclusion from the presently claimed system results in the introduction of new matter.

**Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 18, 20-22, and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 18, 20-22, and 24-27 are indefinite, because there is insufficient antecedent basis for "the metal colloid", which is recited in line 13 of step (c) independent claim 16.

**Response to Arguments**

6. **Rejection of claims 1, 5-10, 12-16, 18, 20-22, and 24-27 under 35 U.S.C. 103(a) based on the combined teachings of Lockhart, Lakowicz, Cao, and Qi**

This rejection has been withdrawn in view of the amendments to independent claims 1 and 16, which require providing a system consisting of a layer of immobilized metal particles on a surface of a substrate, wherein the metal particles are attached to capture probes, each of which have the same length and nucleotide sequence. Since the combined teachings of the above references do not suggest providing the required surface, the previously made rejection has been withdrawn. Accordingly, Applicant's arguments at pages 6-14 of the response filed on January 6, 2011 regarding the rejection have been considered, but they are moot in view of the withdrawal of the rejection.

**Rejection of claims 1, 5-10, 12-16, 18, 20-22, and 24-27 under 35 U.S.C. 103(a) as based on the combined teachings of Cao, Lakowicz I, and Lakowicz II**

Applicant's arguments, see pages 17-18, have been fully considered and are persuasive. As discussed by Applicant at pages 17-18, there is insufficient motivation to replace the Raman-based detection method of Cao with a fluorescence-based detection method. Accordingly, the rejection has been withdrawn.

### **Conclusion**

7. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Bertagna whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela M. Bertagna/  
Examiner, Art Unit 1637